Public Citizen

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Joan Claybrook, President

Dec. 6, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane — Room 1061
Rockville, MD 20852

Re: Docket No. 99F-1912 — "Irradiation in the Production, Processing and Handling of Food"

To whom it may concern:

Under the provisions of 21 CFR §12, Public Citizen is requesting a formal evidentiary public hearing for the purposes of revoking the Food and Drug Administration's Final Rule on Docket No. 99F-1912 — "Irradiation in the Production, Processing and Handling of Food" (65 FR 71056).

We have identified and seek to present at a public hearing genuine and substantial issues containing evidence that raises material issues of fact and questions in a material way the rationale of this ruling.

(1) In its ruling, the FDA did not establish a "safety factor in applying animal experimentation data to man of 100 to 1 ... that is, a food additive for use by man will not be granted a tolerance that will exceed $1/100^{th}$ of the maximum amount demonstrated to be without harm to experimental animals," as required by 21 CFR §170.22. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(2) In its ruling, the FDA did not follow the "principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council," as required by 21 CFR §170.20. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(3) In its Final Rule, the FDA stated: "the agency finds that any photochemical changes that may occur as a result of the UV irradiation are of no toxicological significance" (65 FR 71056). This conclusion was based on no independent analysis by the FDA of toxicological data. The only analysis referenced by the FDA was that conducted by the petitioner, which, according to an October 27, 1999 memorandum by FDA staff member Elke Jensen, stated that "reaction products ... are formed in lower concentrations in irradiation juices than in heat-treated juices

99F-1912

Ralph Nader, Founder

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because photochemical reactions have small quantum yields." No specific data was provided or analyzed to support this assertion. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(4) In its Final Rule, the FDA made no mention of the nutritional changes undergone by juices exposed to radiation. This is of concern for two reasons:

(a) According to an October 27, 1999 memorandum by FDA staff member Elke Jensen, data submitted by the petitioner based on one sample revealed the following vitamin losses:

- Orange juice: 48 percent decrease in ß-carotene, 13 percent decrease in vitamin C, 10 percent decrease in vitamin A.
- Garden vegetable juice: 6 percent decrease in vitamin A.

This information was not referenced in the FDA's Final Rule. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(b) Additionally, Jensen wrote in her October 27, 1999 memorandum:

> "[D]ata presented [by the petitioner] ... are the results of a single sample analysis. Normally, this would not be considered adequate to demonstrate reliable evidence of the destruction (or lack thereof) of vitamins in juices. Because only one sample of juice was tested for the effects of irradiation and the petition does not convey any information about the variability associated with the analytical methods, the reported nutrient levels are unreliable. ... [The petitioner] should analyze the ascorbic acid (vitamin C) content of no fewer than three batches of citrus juice before and after irradiation, in triplicate. Analogous data should be provided regarding the vitamin A content of vegetable juices. ...The petitioner should submit HPLC chromatograms and/or fluorescence spectra, validation data based on the results of the analysis of standard or reference solutions to show that their methods are valid in the concentration range in which they are testing the samples, information or data characterizing the variability of the method (e.g., means, ranges of results, standard deviations), and any calculations used to obtain the results."

Based on the reading of the FDA's Final Rule and the memoranda written by FDA staff members, these recommendations were not followed. Public Citizen is requesting a formal evidentiary public hearing on this matter.

(5) FDA staff member Elke Jensen wrote in a October 27, 1999 memorandum: "UV light, upon passage through air, produces ozone (O_3). Ozone can have deleterious effects on humans who may be exposed to it (e.g., via inhalation), and may have undesirable effects on organoleptic

qualities of the juice. [The petitioner] proposes to include a limitation in the regulation that no ozone be produced. The existing regulation (§179.39) includes an ozone restriction." Jensen wrote that, for "the new entry in §179.39," the list of "Limitations" for "Fruit and vegetable juices" should include "without ozone production."

In its Final Rule, however, the FDA did not include "without ozone production" among its list of "Limitations" for "Juice products" (65 FR 71058). Public Citizen is requesting a formal evidentiary public hearing on this matter.

Taken together, these flaws in the FDA's ruling represent genuine and substantial issues containing evidence that raises material issues of fact and questions in a material way the rationale of the ruling. We request that a formal evidentiary public hearing be held at the earliest possible date.

Respectfully submitted,

Wenonah Hauter
Director
Public Citizen's Critical Mass Energy and Environment Program

any residue from the raw agricultural commodity in the processing (such as by peeling or washing) and so long as the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. But when the concentration of residue in the processed food when ready to eat is higher than the tolerance prescribed for the raw agricultural commodity, the processed food is adulterated unless the higher concentration is permitted by a tolerance obtained under section 409 of the Act. For example, if fruit bearing a residue of 7 parts per million of DDT permitted on the raw agricultural commodity is dried and a residue in excess of 7 parts per million of DDT results on the dried fruit, the dehydrated fruit is adulterated unless the higher tolerance for DDT is authorized by the regulations in this part. Food that is itself ready to eat, and which contains a higher residue than allowed for the raw agricultural commodity, may not be legalized by blending or mixing with other foods to reduce the residue in the mixed food below the tolerance prescribed for the raw agricultural commodity.

Subpart B—Food Additive Safety

§ 170.20 General principles for evaluating the safety of food additives.

(a) In reaching a decision on any petition filed under section 409 of the Act, the Commissioner will give full consideration to the specific biological properties of the compound and the adequacy of the methods employed to demonstrate safety for the proposed use, and the Commissioner will be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner's having followed procedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to the anticipated levels and patterns of consumption of the additive specified or reasonably inferrable. For the purposes of this section, the principles for evaluating safety of additives set forth in the abovementioned publications will apply to any substance that may properly be classified as a food additive as defined in section 201(s) of the Act.

(b) Upon written request describing the proposed use of an additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a food additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 170.22 Safety factors to be considered.

In accordance with section 409(c)(5)(C) of the Act, the following safety factors will be applied in determining whether the proposed use of a food additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor in applying animal experimentation data to man of 100 to 1, will be used; that is, a food additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum amount demonstrated to be without harm to experimental animals.

§ 170.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

§ 107.440 Standards governing prior SBA approval for a proposed transfer of Control.

* * * * *

(c) Require compliance with any other conditions set by SBA, including compliance with the requirements for minimum capital and management-ownership diversity as in effect at such time for new license applicants.

Dated: November 16, 2000.

Aida Alvarez,

Administrator.

[FR Doc. 00–30415 Filed 11–28–00; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 99F–1912]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ultraviolet (UV) irradiation to reduce human pathogens and other microorganisms in juice products. This action is in response to a food additive petition filed by California Day-Fresh Foods, Inc.

DATES: This rule is effective November 29, 2000. Submit written objections and requests for a hearing by December 29, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3088.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 25, 1999 (64 FR 34258), FDA announced that a food additive petition (FAP 9M4676) had been filed by California Day-Fresh Foods, Inc., 533 West Foothill Blvd., Glendora, CA 91741. The petitioner proposed that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of UV light to reduce human pathogens and other microorganisms in juice products.

II. Safety Evaluation

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. The additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction of human pathogens and other microorganisms in juice products.

A. Toxicology

FDA has evaluated the safety of the use of UV irradiation to reduce human pathogens and other microorganisms in juices. This safety assessment was based on the current understanding of the effects of UV irradiation on the major chemical components of food. Having evaluated the data in the petition and other relevant material in the agency's files, the agency finds that any photochemical changes that may occur as a result of the UV irradiation are of no toxicological significance (Ref. 1).

B. Microbiology

The petitioner submitted data demonstrating the reduction of specific pathogens (*Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*) inoculated into four types of juices (orange, apple, carrot, and garden vegetable). These four juice varieties are representative of the types of juice that are consumed by the U.S. population and that could be treated with UV irradiation (Ref. 2). After UV irradiation, there were significant reductions in pathogens. FDA concludes that the proposed use is effective in reducing human pathogens in juices and that treated juices will be at least as safe as untreated juices currently on the market (Ref. 3). However, the submitted microbiological data do not constitute the type of validation studies necessary to demonstrate the achievement of specific performance standards, *e.g.* 5-log reductions, for human pathogen control programs (Ref. 3). Therefore, users of this UV treatment who are subject to certain performance standards will need to establish that this treatment meets their required level of human pathogen reduction.

C. Specifications for Use

The petitioned UV radiation is produced by low pressure mercury lamps, which emit more than 90 percent of their light at 253.7 nanometers (nm) (2,537 Angstroms); juice being treated passes through a transparent tube in which the juice is subjected to UV irradiation. Because most juices strongly absorb UV radiation, most of the UV radiation would be absorbed by the juice at the wall of the tube near the source of the UV irradiation. However, the amount of UV irradiation that would reach juice in the middle of the tube would be insufficient to reduce significantly human pathogens. Therefore, the petitioner proposed that the juices flow under turbulent conditions that produce eddies and swirls in the juice to ensure that as much juice as possible will reach the wall of the UV transparent tube where the juice would be exposed to UV irradiation. This would help to reduce human pathogens and other microorganisms throughout the juice. The conditions for turbulent flow are described mathematically by the unitless Reynolds number (Re):

ER29NO00.001

where:
D is the tube diameter,
u is fluid velocity,
p is fluid density, and
μ is fluid viscosity.

To ensure that sufficient turbulent flow is achieved, the petitioner has requested that a limit of a Reynolds number of no less than 2,200 be incorporated into the regulation. FDA concurs with this specification (Ref. 4).

The amount of UV irradiation necessary for human pathogen reduction will depend on various factors, such as the type of juice, the initial microbial load, and the design of the irradiation system (*e.g.*, flow rate, number of lamps, and time exposed to irradiation). Therefore, FDA is not specifying a minimum or maximum dose by regulation, but concludes that this should be achieved for individual usage situations in a manner consistent with good manufacturing practice (Ref. 5). FDA expects that the maximum dose applied to the juice will be economically self-limiting due to the costs associated with UV irradiation. Additionally, the levels of UV irradiation applied to the juice will be limited by the possible alterations in organoleptic characteristics of the juice (*i.e.*, changes in taste or color) after UV irradiation, changes that may result in decreased consumer acceptance. Thus,

juice processors will also limit the maximum applied dose of UV irradiation to avoid production of a product not acceptable to consumers (Ref. 5).

Based on the data and studies submitted in the petition and other information in the agency's files, FDA concludes that the proposed use of UV irradiation of juice products is safe, that the irradiation will achieve its intended technical effect, and therefore, that the regulations in § 179.39 should be amended as set forth below.

D. Other Changes to § 179.39

FDA is also making an editorial change to the existing regulation to describe more accurately the approved emission sources and to remove an unnecessary and confusing description. This change does not affect the nature or properties of permitted sources. Currently, § 179.39(a) stipulates that "The radiation sources consist of ultraviolet emission tubes designed to emit wavelengths within the range of 2200–3000 Angstrom units with 90 percent of the emission being the wavelength 2537 Angstrom units." The stipulation that 90 percent of the emission is at 253.7 nm (2,537 Angstroms) is sufficient to describe the sources as low pressure mercury lamps. Furthermore, since a small percentage of the emission from these tubes is outside of the 220.0 to 300.0 nm (2,200 to 3,000 Angstroms) range, this restriction is factually inaccurate. Therefore, FDA is removing the restriction of the wavelength range in § 179.39(a) and in the table in paragraph (b) under the "Limitations column," and is instead specifying that the source of the irradiation to be low pressure mercury lamps.

III. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the Filing Notice for FAP 9M4676 (June 25, 1999, 64 FR 34258). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by December 29, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA Memorandum, A. Mattia to W. Trotter, November 2, 1999.
2. FDA Memorandum, E. Jensen to W. Trotter, September 6, 2000.
3. FDA Memorandum, R. Merker to W. Trotter, January 26, 2000.
4. FDA Memorandum, E. Jensen to W. Trotter, October 27, 1999.
5. FDA Memorandum, E. Jensen to W. Trotter, October 27, 2000.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.39 is amended by revising paragraph (a) and by revising the table in paragraph (b) to read as follows:

§ 179.39 Ultraviolet radiation for the processing and treatment of food.

* * * * *

(a) The radiation sources consist of low pressure mercury lamps emitting 90 percent of the emission at a wavelength of 253.7 nanometers (2,537 Angstroms).

(b) * * *

Irradiated food	Limitations	Use
Food and food products	Without ozone production: high fat-content food irradiated in vacuum or in an inert atmosphere; intensity of radiation, 1 W (of 2,537 A. radiation) per 5 to 10 $ft.^2$	Surface microorganism control.

Irradiated food	Limitations	Use
Potable water	Without ozone production; coefficient of absorption, 0.19 per cm or less; flow rate, 100 gal/h per watt of 2,537 A. radiation; water depth, 1 cm or less; lamp-operating temperature, 36 to 46 °C.	Sterilization of water used in food production.
Juice products	Turbulent flow through tubes with a minimum Reynolds number of 2,200.	Reduction of human pathogens and other microorganisms.

Dated: November 14, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–30453 Filed 11–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD11–00–016]

RIN 2115–AE46

Special Local Regulations: San Diego Christmas Boat Parade of Lights

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements 33 CFR 100.1101, Southern California annual marine events, for the San Diego Christmas Boat Parade of Lights. The event will consist of private vessels approximately 10 to 60 feet in length with Christmas lights formed in a parade through the San Diego Harbor. These regulations will be effective on that portion of San Diego Harbor, from the northern portion of the main channel from Seaport Village to the Shelter Island Yacht Basin. Notice of Implementation of 33 CFR 100.1101 is necessary to control vessel traffic in the regulated areas during the event to ensure the safety of participants and spectators.

Pursuant to 33 CFR 100.1101(b)(3), Commanding Officer, Coast Guard Activities San Diego, is designated Patrol Commander for this event; he has the authority to delegate this responsibility to any commissioned, warrant, or petty officer of the Coast Guard.

EFFECTIVE DATES: This section is effective on December 10, 2000 from 2:00 p.m. (PST) until 10:00 p.m. (PST) and on December 17, 2000 from 5:00 p.m. until 10:00 p.m. (PST). If the event concludes prior to the scheduled termination date and/or time, the Coast Guard will cease enforcement of this section and will announce that fact via Broadcast Notice to Mariners.

FOR FURTHER INFORMATION CONTACT: Petty Officer Nicole Lavorgna, U.S. Coast Guard MSO San Diego, San Diego, California; Telephone: (619) 683–6495.

Discussion of Implementation. These Special Local Regulations permit Coast Guard control of vessel traffic in order to ensure the safety of spectator and participant vessels. In accordance with the regulations in 33 CFR 100.1101, no persons or vessels shall block, anchor, or loiter in the regulated area; nor shall any person or vessel transit through the regulated area, or otherwise impede the transit of participant or official patrol vessels in the regulated area, unless cleared for such entry by or through an official patrol vessel acting on behalf of the Patrol Commander.

Dated: November 21, 2000.

C.D. Wurster,

U.S. Coast Guard, Commander, Eleventh Coast Guard District, Acting.

[FR Doc. 00–30446 Filed 11–28–00; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–00–026]

RIN 2115–AE47

Drawbridge Operating Regulation; Neches River, TX

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is issuing this rule as a matter of information to the public. The Kansas City Southern Lift Bridge across the Neches River, mile 19.5, in Beaumont, TX is currently controlled from a remote location. The owner of the bridge, The Kansas City Southern Railway Company operates the bridge from their dispatch office in Shreveport, LA. This rule provides the public with a complete description of the operation of this bridge.

DATES: This rule becomes effective on November 29, 2000.

ADDRESSES: Documents referred to in this rule are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 501 Magazine Street, New Orleans, Louisiana 70130–3396 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. Commander (ob) maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Mr. David Frank, Bridge Administration Branch, telephone number 504–589–2965.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM.

An NPRM is not necessary because this rule makes no substantive changes to the operation of the Kansas City Southern Lift Bridge, but it does describe the full remote operation of the bridge for the benefit of the public.

Background and Purpose

The Kansas City Southern Lift Bridge across the Neches River, mile 19.5, in Beaumont, TX is a remotely operated railroad bridge that opens to navigation on demand. The owners of the bridge, The Kansas City Southern Railway Company operates the bridge remotely from Shreveport, LA and has installed a sound device that transmits the vessel signals for an opening to the bridge operator. Then, through this same device, the bridge operator can respond whether the bridge can be opened at that time or not. No changes will be made to how the bridge currently operates.

For the benefit of the public, the Coast Guard is adding a description of the full operation of this remotely operated bridge to 33 CFR 117 subpart b.

DEPARTMENT OF H ALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date October 27, 1999

From Division of Product Manufacture and Use (HFS-246)
Chemistry Review Team

Subject **FAP 9M4676** (MATS M2.0 & 2.1): Use of ultraviolet light in the reduction of microorganisms in juice products (submissions of May 10, 1999 and August 25, 1999 from California Day-Fresh Foods, Inc.).

To Division of Product Policy
Attn.: William J. Trotter, Ph.D.

1. INTRODUCTION

California Day-Fresh Foods, Inc. (CDFF) has submitted a petition to amend the food additive regulations at 21 CFR 179.39, *Ultraviolet light for the processing and treatment of food*, to allow for the use of ultraviolet irradiation to reduce the microbial contamination of fruit and vegetable juices. Currently, this regulation allows light at wavelengths between 2200 Å (220 nm) and 3000 Å (300 nm) to be used for surface microbial control in high fat-content foods and potable water.

2. IDENTITY

Mercury (Hg) vapor lamps, provide ultraviolet (UV) radiation between 248 nm and 578 nm. The petition includes a table showing the various emission lines in this region and their corresponding intensities. The most intense Hg atomic line in this region is at 253.7 nm, which accounts for approximately 90% of the intensity of emitted light.

The description of the additive is acceptable.

3. PRODUCTION OF UV LIGHT

CDFF intends to use UV light at 253.7 nm produced by Hg-vapor lamps. The petitioner states that its design uses a dozen lamps that emit 26 W in the UV range, with approximately 90% of the UV light generated at 253.7 nm (specified by the lamp manufacturer, page 14). Although the power output of any lamp is expected to decrease over its operating lifetime, CDFF proposes that a minimum radiation dose be specified in the regulation to ensure that juices would receive adequate dosages to achieve the intended antimicrobial effect.

UV light, upon passage through air, produces ozone (O_3). Ozone can have deleterious health effects on humans who may be exposed to it (e.g., *via* inhalation), and may have undesirable effects on organoleptic qualities of the juice. CDFF proposes to include a limitation in the regulation that no ozone be produced. The existing regulation (§179.39) includes an ozone restriction.

We have no questions regarding the method of producing UV light.

4. FLOW CONSIDERATIONS

To accomplish the irradiation, juice is flowed through coiled Fluorinated Ethylene Propylene (FEP) Teflon tubing. This material is transparent to UV light in the wavelength range of interest. Arranged around the coil are Hg-vapor lamps that produce the 253.7 nm light, which is focussed into the tubing.

CDFF notes that most juices strongly absorb UV light, so that under laminar (smooth) flow conditions, only the outermost 0.05-0.1 inches of juice would be irradiated, and insufficient light would reach juice in the middle of the tube to kill microorganisms. CDFF, therefore, proposes to flow juices under turbulent conditions that will produce eddies and swirls in the juice. Turbulence will cause "new" juice to be constantly forced to the side of the tubing, and thus "fresh" juice will constantly be exposed to the UV light.

The conditions for turbulent flow are given by the Reynolds number, Re. The dimensionless Reynolds number is given by the following expression:

$$R_e = \frac{D\ u\ \rho}{\mu}$$

where D = the tube diameter, u = fluid velocity, ρ = fluid density, and μ = fluid viscosity. Turbulent flow is achieved at Reynolds numbers larger than about 2000. To ensure that turbulent flow is achieved, the petitioner has requested that a limit of a Reynolds number of not less than 2200 be incorporated into the regulation. Users of the flow system described in the petition would ensure turbulent flow by measuring the flow parameters of their system (e.g., D, u, ρ, and μ) and calculating Re. CDFF has provided data characterizing their system, showing, for example, the change in flow rate versus viscosity at a constant Reynolds number.

The specification for the minimum Reynolds number is acceptable.

5. RADIATION DOSES

UV irradiation is intended to reduce the number of microorganisms in juice. The petitioners are requesting that juices be treated with a UV dose between 30,000 and 300,000 μW-sec/cm^2 (μJ/cm^2) at 253.7 nm. These limits are intended to establish a minimum below which little or no antimicrobial effect would be achieved, and a maximum dose above which important nutrients may decompose and undesirable organoleptic properties of the juice would be introduced. CDFF states that the upper limit is about 6% lower than the upper limit established in the regulation for pulsed UV light (§179.41, *Pulsed light for the treatment of food*), and reasons that this level of radiation

for treating food has already been evaluated as safe.

In Table A-1 (pages 82-84), CDFF compiled a list of radiation doses expected to result in 3-log kills of various microorganisms and prevent colony formation. This table is intended to show which microorganisms will be affected by the proposed radiation doses and provide a basis for comparison of their sensitivity to irradiation. Doses for a 3-log kill range from 2,500 to 440,000 $\mu W\text{-sec}/cm^2$ ($\mu J/cm^2$).[1] CDFF calculated that at an intensity of 1 W/5 ft^2 (215 $\mu J/s\text{-}cm^2$), these doses correspond to exposure times of 2.32 minutes, and 23.13 minutes, respectively (page 74). CDFF estimated an average intensity inside the tubing of 15,200 $\mu W/cm^2$ (page 9). For this intensity, the exposure time needed to yield a dose of 30,000 $\mu W\text{-sec}/cm^2$ ($\mu J/cm^2$) would be only two seconds. As discussed above, however, turbulent flow is required to ensure that all of the juice be exposed to the UV light. This means that any given volume of juice is not continuously exposed to the UV light. Longer exposures, therefore, would ensure that all of the juice in the system would be adequately irradiated.

The specified range of UV doses is acceptable.

6. EFFICACY

UV irradiation of food is intended to reduce microbial contamination in fruit and vegetable juices. The petitioner requests a general listing for juices that clearly covers a variety of products, and has tested a set of juices intended to represent many juices: carrot, apple, orange, and garden vegetable mix juices. The petitioner also claims improved shelf-life of juice products can be achieved by using radiation, and provides summary data to support its claim (page 000048). CFSAN microbiologists are reviewing the efficacy data.

7. OTHER EFFECTS OF UV EXPOSURE ON JUICES

The petitioner addressed whether reactions may occur upon exposure to UV light other than those that take place under normal heat processing (section E). CDFF tested for changes in enzyme activity and evidence of decreased nutrient content, and considered the possibility that nucleic acid bases and amino acids would absorb light and undergo subsequent reactions to produce undesirable compounds. These three possibilities are discussed below.

a. Enzyme activity

CDFF evaluated the effects of irradiation on enzymes to show that irradiation induces less damage to juices than pasteurization. Although enzymes are denatured

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[1] As noted above, the upper limit on the doses would be 298,816 $\mu W\text{-sec}/cm^2$. Only one organism listed in the table, tobacco mosaic virus, requires a level of exposure over the upper limit to achieve the 3-log reduction.

during heat-processing, and this effect by itself would not necessarily be of concern, denaturation *via* UV irradiation could imply the possibility that the amino acids were undergoing reactions because of irradiation (see also part c of this section). Amino acids that comprise enzymes have moderate UV-absorption cross-sections, and may undergo a chemical change upon absorption of a photon. Thus, if amino acids in the enzymes absorbed light, and subsequently reacted, a loss of enzyme activity might be observed.

CDFF tested the effects of irradiation on the levels of alkaline phosphatase and acid phosphatase enzyme activity. The petitioner stated that these enzymes were selected because they are commonly found in biological systems. Enzyme activities in irradiated juices were compared with those heat-treated juices (as a positive control), in which the enzymes are inactivated, and untreated juices (as a negative control), in which enzymes are expected to remain active. Enzyme activity was evaluated by measuring the rate of formation of an enzyme-catalyzed reaction by visible absorption.

Irradiation of carrot, green mix, and garden vegetable juices fractionally decreased enzyme activities for both acid and alkaline phosphatases. For comparison, heat pasteurization results in complete deactivation of enzymes. CDFF concluded that the changes in enzyme activity in radiation-treated juices are not significant. We agree with the petitioner's conclusion.

b. Nutrient content

CDFF evaluated the vitamin contents of treated and untreated juices. The results shown on pages 000065-6 focus on those vitamins they expected to be light-sensitive. Values for the following analyses were reported: orange juice - A, β-carotene, B1, B2, B6, C, E, and folic acid; apple juice - B1, B2, B6, and C; garden vegetable juice - A, β-carotene, retinol, C, E, and folic acid; and carrot juice - A, β-carotene, retinol, and C.

CDFF submitted an amendment to the petition (submission of August 25, 1999), that included detailed protocols for the analytical methods used to measure nutrient content in the juices. Protocols for the following nutrients were provided: vitamin A by HPLC, beta-carotene by HPLC, vitamin B6 by microbial assay with turbidimetric measurement, vitamin C (ascorbic acid) by fluorescence, vitamin E (tocopherol) by HPLC, folic acid by microbiological assay with turbidimetric measurement, pantothenic acid by microbiological assay, niacin by microbiological assay, thiamine by fluorescence, and riboflavin by fluorescence and by HPLC. The descriptions of the methods provide directions for extraction from foods, and instructions for preparing standards. The methods are acceptable.

Based on a telephone conversation with the petitioner, we understand that the data presented in the tables on pages 000065-66 are the results of a single sample analysis. Normally, this would not be considered adequate to demonstrate reliable

evidence of the destruction (or lack thereof) of vitamins in juices. Because only one sample of juice was tested for the effects of irradiation and the petition does not convey any information about the variability associated with the analytical methods, the reported nutrient levels are unreliable. The implications of this deficiency will be discussed at the end of this subsection. The next paragraphs summarize the petitioners discussion of the data and their conclusions about its significance. We will then present our own discussion of nutrient intakes, including the potential impact of irradiation on the overall nutritional status of juice consumers.

CDFF states that they do not expect juices to be significant sources of the fat-soluble vitamins (A, D, E, K, and beta-carotene), except for vitamin A from vegetable juices. CDFF noted that the changes in the vitamin content for apple juice were not considered significant because this product does not contribute significantly (>2%) to the RDA for these vitamins.

The following changes in vitamin content were reported for orange juice: a 13% decrease in vitamin C, a 10% decrease in vitamin A, and a 48% decrease in β-carotene. Most consumers who drink orange juice recognize it as a good source of vitamin C, and seek other sources of vitamin A (such as tomatoes). According to the petitioner, since 8 ounces of orange juice contributes 210% of the current RDA for vitamin C, and only 10% of the RDA for vitamin A, the observed changes in the nutrient levels are not expected to have a deleterious effect on the intakes of these nutrients.

apple?

For Garden Vegetable juice, vitamin A decreased about 6%. Since eight ounces of this type of juice would provide about 560% of the RDA for vitamin A, the petitioner concluded that this change would not adversely affect overall nutrient intakes from these juices.

The reported level of vitamin A in irradiated carrot juice was higher than in untreated juice. We expect that this is an artifact of the experiment. Since 8 ounces of carrot juice provides 690% of the RDA for vitamin A, the petitioner concluded that irradiation of carrot juice would not reduce dietary vitamin A intake. From USDA food consumption survey data, consumption of carrot juice is limited to a very small fraction of the population (less than 1%), and although high in vitamin A, does not contribute significantly to the overall dietary intake of vitamin A for US consumers in general.

We performed nutrient analyses[2] to estimate the effects of changes in vitamin content in citrus and vegetable juices on vitamin C intakes and on vitamin A intakes, respectively. The results are tabulated in Table 1. The intake of preformed vitamin A is

[2] The USDA's 1989-92 Continuing Survey of Food Intakes by Individuals (CSFII) is a three-day survey including a one-day recall and a two-day diary.

calculated as the difference between the total vitamin A activity and beta-carotene content reported from the USDA-based calculations. For the sake of comparison, the adult RDA for ascorbic acid is 60 mg/p/d, and the RDA for vitamin A is 1000 RE/p/d. Although the nutritional importance of beta-carotene is uncertain and no RDA has been established for carotenoids, the vitamin A activity from vegetables is attributable principally to beta-carotene and, to a lesser extent, other carotenoids, not to retinol or retinyl esters (e.g., preformed vitamin A).[3]

Table 1: Current nutrient intakes based on USDA survey data

	Citrus Juices	Vegetable juices		
	Vitamin C (ascorbic acid, mg/p/d)	Preformed Vitamin A‡, RE/p/d (by difference)	Beta-carotene, RE/p/d	Total Vitamin A* RE/p/d
Average nutrient intake, only from this food (eaters-only)	61	0	100.6	100.6
Total average nutrient intake for eaters of this food	131	587	701	1288
Total average nutrient intake for non-eaters of this food	70	543	413	960

‡ Retinol and retinyl esters.
* The intake of total vitamin A is the sum of the intake of preformed vitamin A (retinol, retinyl esters) and the consumed beta-carotene.

From this table, it can be seen that, on average, vegetable juices contribute about 10% of overall vitamin A intake for consumers who eat those products. If all the vitamin A in vegetable juice was destroyed (100.6 RE/p/d), this would decrease the overall vitamin A intake of vegetable juice consumers (1288 RE/p/d) to 1188 RE/p/d. Similarly, if all the ascorbic acid consumed from citrus juices (61 mg/p/d) were

[3] The vitamin A activity could also be attributed to other pre-vitamin A carotenoids, such as alpha- or gamma-carotene, or certain other carotenoids. Retinol and retinyl esters, "pre-formed vitamin A" are, however, obtained directly principally from animal products, such as meat and dairy products, or manufactured synthetically. (Personal communication with K. Egan, FDA, 28 Sept. 1999)

destroyed, the overall dietary intake of ascorbic acid for those consumers (131 mg/p/d) would decrease to about 70 mg/p/d.

We also performed a nutrient analysis using USDA food consumption survey data to estimate the daily intake of vitamin A by consumers who drink orange juice and the relative contribution of vegetable juice to overall vitamin C intake. The data are tabulated in Table 2, below. The analysis shows that the average dietary intake of vitamin A by orange juice consumers is more than 1,000 RE total vitamin A and that citrus juices contribute little to the overall intake.

Table 2: Current nutrient intakes based on USDA survey data

	Vegetable juices	Citrus Juices		
	Vitamin C (ascorbic acid, mg/p/d)	Preformed Vitamin A‡, RE/p/d (by difference)	Beta-carotene, RE/p/d	Total Vitamin A* RE/p/d
Nutrient intake, only from this food (eaters-only)	26	0	15	15
Total nutrient intake for eaters of this food	123	566	466	1032
Total nutrient intake for non-eaters of this food	91	537	393	930

‡ Retinol and retinyl esters.
* The intake of total vitamin A is the sum of the intake of preformed vitamin A (retinol, retinyl esters) and the consumed beta-carotene.

The data in Table 2 also show that destruction of all the vitamin C in vegetable juices would reduce the total vitamin C intake for vegetable juice consumers from 123 mg/p/d to about 97 mg/p/d (123 - 26 mg/p/d). The table also clearly shows that citrus juices contribute only a tiny fraction (about 1%) of the total vitamin A intake (15 RE/p/d vs. 1030 RE/p/d). Since even a 100% decrease in vitamin A in citrus juices would not significantly reduce consumers' overall intakes of this nutrient below the RDA, we conclude that any decrease in vitamin A in citrus juice resulting from UV-irradiation will also not affect consumer intakes.

This information may be brought to the attention of our nutritionists.

As noted earlier, only one sample of each juice was tested for changes in nutrient content upon irradiation. Although the data on nutrient intakes above suggest that the safety evaluation will not need to rely on quantitative information about the level of nutrient destruction by irradiation, labeling and nutrient-claim considerations for treated juices may require an analysis of properly collected and validated data. Such data will also permit the evaluation of the variability associated with such methods. To this end, CDFF should analyze the ascorbic acid (vitamin C) content of no fewer than three batches of citrus juice before and after irradiation, in triplicate. Analogous data should be provided regarding the vitamin A content of vegetable juices. The analytical methods should be validated in the relevant concentration range. A complete package would include spectra or chromatograms for each batch analysis, the validation data, any calculations performed to manipulate the data, and a discussion of the statistical significance of the results.

c. Other Changes to Juice Components

The petitioner considered the possibility that undesirable photochemical changes might take place upon irradiation of juices. For example, a comparison of the energy of the incident photons (113 kcal/mol) to the bond energies of various chemical bonds show that certain bonds may be broken (O-H, C-C, C-H, C-N, N-H, and S-S, page 68). CDFF discounts reactions such as formation of radicals and oxidation, because the juice is self-contained in the flow system, and little or no oxygen is present. Although less oxygen is likely to be present in juices contained in a closed flow system than those open to air, the dissolved oxygen content will be significant unless the juice had been deoxygenated before processing. Thus, the possibility remains that the juices could undergo some oxidation or radical formation upon irradiation. However, the extent of these reactions is likely less under the described conditions of treatment than under normal conditions of heat pasteurization.[4]

Overall, the likelihood of a bond breaking upon irradiation depends on the probability of absorbing a photon and the probability of the reaction taking place. (Competing reactions offer alternative routes of distributing the energy imparted by the photon, such as fluorescence, heating, or molecular rearrangement.) CDFF outlines their considerations on page 68.

The petitioner concluded that, based on the concentration of nucleic acid bases, and the absorption cross-sections (probabilities) of adenine, guanine, thymine, cytosine, and uracil, nucleic acid bases would absorb about 90% of incident light. (Amino acids would absorb most of the remaining 10% of the incident light.) The petitioner states that the two principal changes would be formation of pyrimidine dimer and "6-4 photo products" (described as two covalently bonded pyrimidines), but that these products

[4] Oxidation is also likely to affect organoleptic qualities of juice products (e.g., taste and color).

undergo no known subsequent reactions. Nucleic acid bases are present in cells at similar concentrations as amino acids (about 0.5 g/L) but typically have smaller quantum yields, on the order of 0.001.[5]

CDFF states that although amino acids would absorb only about 10% of the incident light, they have a much higher probability of undergoing subsequent reactions than nucleic acid bases. They state that of all the amino acids, tryptophan and cystine are the most "photosensitive" (absorbing and reactive) amino acids. Reaction products from these species include hydrogen sulfide, ammonia, and hydrogen peroxide, among others (page 70). CDFF states that the weight percentages of these two amino acids in juices are small (<1 gm/L) and that the reaction products are the same as those produced by heat-treatment of juices. The petition states that these products are formed in lower concentrations in irradiated juices than in heat-treated juices because the photochemical reactions have small quantum yields. CDFF supports their conclusions with the results of the enzyme analysis (above) in which they claimed that changes to these proteins were small, even after long exposures to UV light (15 minutes).

We agree with the petitioner's conclusion that UV irradiation at the proposed dosages will not result in the production of harmful substances in the juices. With respect to the effects of irradiation on nutrients, however, the petitioner should be asked to provide the complete and validated replicate data on the effects of irradiation as described above.

8. PROPOSED REGULATION

CDFF proposes to amend §179.39 to include an entry for "juice products" subject to the following limitations:

- An irradiation wavelength range of 2480-3660 Å;
- No ozone production;
- Minimum Reynolds number (R_e) of 2200;
- Radiation intensity between 30,000 and 300,000 μW-sec/cm^2 at 2537 Å.

We believe that the specification of a minimum irradiation dosage is not necessary because antimicrobial efficacy is strongly dependent upon the initial microbial load in the food. We recommend, therefore, that the new entry in §179.39 read as follows:

[5] Quantum yield is the ratio of photons absorbed that cause a reaction compared to the number of absorbed photons.

Irradiated food	Limitations	Use
* * *	* * *	* * *
Fruit and vegetable juices	Irradiated with 2480 to 3660 Å (248.0-366.0 nm) emissions, without ozone production; intensity of radiation, not more than 300,000 μW-sec/cm^2 at 2537 Å (253.7 nm), in an enclosed system. Under turbulent flow conditions with a Reynolds number, R_e (dimensionless), not less than 2200, where $R_e = \frac{D\ u\ \rho}{\mu}$ and D = the tube diameter, u = fluid velocity, ρ = fluid density, and μ = fluid viscosity.	Microbial control.
* * *	* * *	* * *

9. SUMMARY

California Day-Fresh Foods has proposed a method to UV-irradiate fruit and vegetable juices for reducing microbial contamination. In juices that are strong UV absorbers, the light may not penetrate beyond the topmost 0.1 inches. The petitioned method uses turbulent flow that will cause "new" juice constantly to be exposed to the UV light source.

CFSAN microbiologists are evaluating the petition with respect to antimicrobial efficacy and the claims that irradiation can extend shelf-life.

The petitioner has tested various irradiated juices for changes to enzymes, vitamins, and other components (amino acids, etc.) of the juices. The petitioner should be asked to provide complete data on the effects of irradiation on ascorbic acid (vitamin C) content in a representative citrus juice (e.g., orange juice) and for vitamin A content of a vegetable juice. At least three different batches should be tested (before and after

irradiation), and each analysis conducted in triplicate. The petitioner should submit HPLC chromatograms and/or fluorescence spectra, validation data based on the results of the analysis of standard or reference solutions to show that their methods are valid in the concentration range in which they are testing the samples, information or data characterizing the variability of the method (e.g., means, ranges of results, standard deviations), and any calculations used to obtain the results.

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